

## REMARKS

The Office Action dated January 27, 2009, has been fully considered. The present Response is intended to be a complete response thereto and to place the case in condition for allowance.

Claims 1-3 and 10-17 are pending. Claims 4-9 have been cancelled.

### THE CLAIMS ARE NOT ANTICIPATED OF OBVIOUS

Claims 1-3, 10-13, and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over Borody (U.S. Patent No. 5,443,826). Claims 14-16 stand rejected under 35 U.S.C. § 103(a) as being obvious over Borody in view of Farmer et al. (U.S. Patent No. 7,374,753) and Armel (Cold Pasturization of certain bacteria by radionuclide gamma radiation. Applied Sugar Laboratories. January 1964) Applicant respectfully traverses the rejection.

Brody does not disclose every element of the claimed invention. The current claims “consist of” two steps 1) administering an antimicrobial composition; and 2) subsequently administering a probiotic agent. “The transitional phrase ‘consisting of’ excludes any element, step, or ingredient not specified in the claim.” MPEP 2111.03.

Borody discloses treatment of gastrointestinal disorders by (a) substantially complete removal of existing enteric flora; and (b) introduction of an array of predetermined flora into the gastrointestinal flora to completely change the enteric flora of the patient. Borody, column 3, lines 61-68. With regard to step (a), Borody discloses that

In the practice of the invention the patients [*sic*] existing enteric flora is removed by gastrointestinal lavage effected by ingestion of

about 3 liters of a balanced salt solution with polyethylene glycol. Lavage is continued until the removal of the existing flora is as near complete as possible.

Column 5, lines 34-39. However, in column 5, lines 55-60, that “a preparatory course of appropriate antibiotics may be used,” such as, “Septrin for chronic yersiniasis, Metronidazole for ulcerative colitis, anti-TB therapy in Crohn's disease, or Vancomycin in chronic *Clostridium difficile* infestations.” The preparatory course is used before the removal of the enteric flora. *See, e.g.*, Example 1 (the patient was treated with metronidazole for one week before “oral ingestion of three liters balance salt solution with polyethylene glycol”). Thus, even with the antibiotic treatment, the method of Borody requires three steps (i) antibiotic administration; (ii) gastrointestinal lavage; and (iii) introduction of a predetermined flora.

Thus, Borody discloses two possible methods of practicing his invention. The first method includes (i) removal of the enteric flora by a gastrointestinal lavage; and (ii) introduction of an array of predetermined flora into the gastrointestinal flora to completely change the enteric flora of the patient. The second method requires three steps: (i) preparatory course of antibiotic administration; (ii) removal of existing enteric flora by a gastrointestinal lavage; and (iii) introduction of a predetermined flora.

Neither of those methods anticipate or render the present invention obvious. The first method does not disclose “administering ... an antimicrobial composition effective against the abnormal microorganism” as recited in the present claim 1. A lavage removes the enteric flora mechanically, while the antimicrobial composition of the present invention removes the abnormal microorganism chemically. Additionally, there is no rationale for one of ordinary skill in the art to substitute an antimicrobial composition for the lavage of Borody, nor has the Examiner offered one. This step is essential to his invention. Removal of this step would

eviscerate Borody's teaching. Clearly, Borody teaches that the administration of antibiotic alone is insufficient. The whole existing enteric flora must be removed. (Example 1 discloses mechanical removal of the enteric flora after treating the patient for one week with metronidazole for one week). The administration of the antibiotic "may be used" (column 5, lines 56-57) while the lavage removal of the existing enteric flora is a required step (column 3, lines 61-63) in the method of Borody. Therefore, one of ordinary skill would have no rationale to eliminate the step of removing the enteric flora from the method of Borody.

The second method does not anticipate or render the present invention obvious because it is a three step process. Because the present claims recite the close transitional phrase "consisting of," a three step process cannot anticipate the present invention, because "[t]he transitional phrase 'consisting of' excludes any element, step, or ingredient not specified in the claim." MPEP 2111.03. Here, the lavage step of Borody is clearly excluded by the present claims. Additionally, there is no rationale for one of ordinary skill in the art to eliminate the lavage step in the method of Borody, nor has the Examiner offered one. As mentioned above, this step is essential to his invention. Removal of this step would eviscerate Borody's teaching. Therefore, one of ordinary skill would have no rationale to eliminate the lavage step from the method of Borody.

In the Office Action, page 7, the Examiner alleges that "a reading of Borody can effectively read on two steps and meet the new limitation of "consist of" language." Applicant respectfully submits that the two step process of Borody (the first method discussed above) does not disclose the use "an antimicrobial composition effective against the abnormal microorganism" as recited in claim 1. Borody uses a gastrointestinal lavage. Borody does not disclose the use of antibiotics without a subsequent lavage.

Also on page 7 of the Office Action, the Examiner alleges that the present claims do not recite that the present invention does not remove the existing enteric flora. Applicant respectfully submits that the difference between the present invention and Borody is that the reference uses a gastrointestinal lavage to remove the entire flora and does not use antimicrobial compositions against the abnormal organism. Any use of antibiotic by Borody necessarily must be followed by a gastrointestinal lavage, and thus, result in a three step process (the first method discussed above) that cannot anticipate the present invention.

Also on page 7 of the Office Action, the Examiner states:

With regard to obviousness, as noted above and for these reasons  
Applicants do not omit removal of enteric flora while treating with  
an antibacterial agent. These agents do remove enteric flora.

First, Applicant respectfully submits that the Examiner's allegation that the antimicrobial compositions used in the present invention "do remove enteric flora" is unsupported and is not based on facts. If the Examiner maintains in asserting that statement, Applicants respectfully requests that the Examiner produces facts and references supporting her statement. Second, even if the Examiner's statement is true *arguendo*, Borody does not disclose removal of the enteric flora using an antimicrobial composition. According to Borody, "existing enteric flora is removed by gastrointestinal lavage." Column 5, lines 34-39. Any use of antibiotics by Borody is merely "a preparatory course" prior to the lavage. *See* column 5, lines 55-60; and Example 1.

On page 7 of the Office Action, the Examiner states:

Also one of skill in the art would have been capable of determining  
the optimal antibacterial agent to select dependent upon the  
pathogenic effect desired because they are well known and taught  
in the cited prior art to be effective for treating pathogenic bacteria.

It appears from this statement that the Examiner believes that one of ordinary skill in the art is able to select optimal antibacterial agent to treat a certain pathogen. That skill, however, still

does not provide any rationale why one skilled in the art, based on the disclosure of Borody, would substitute an antimicrobial composition for the lavage of Borody or eliminate the lavage step in the method of Borody. As mentioned above, the gastrointestinal lavage is essential to Borody's invention. Removal of this step would eviscerate Borody's teaching. Further, selecting optimal antibacterial agent to treat a certain pathogen has no applicability to Borody, because he taught removal the intestinal flora rather than just a selected abnormal organism. Clearly, in Borody's view, treatment with antibiotic is insufficient. As such, he discloses antibiotics only as "a preparatory course" to be used prior to the gastrointestinal lavage. *See* column 5, lines 55-60; and Example 1.

With regard to Farmer et al. and Armel, these references do not cure the deficiencies of Borody discuss above. Therefore, their combination with Borody still does not render the present invention obvious.

For the reasons noted, the present invention is not anticipated within the meaning of 35 U.S.C. § 102 or is obvious within the meaning of 35 U.S.C. § 103. Accordingly, Applicant respectfully request withdrawal of the rejections.

## CONCLUSION

Applicant has responded to the Office Action mailed January 27, 2009. All pending claims are now believed to be allowable and favorable action is respectfully requested.

In the event that there are any questions relating to this Amendment or to the application in general, it would be appreciated if the examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (111828.0113). In the event that a petition for an extension of time is required to be submitted herewith and in the event that a separate petition does not accompany this response, applicant hereby petitions under 37 C.F.R. 1.136(a) for an extension of time.

Any fees due are authorized above.

Respectfully submitted,

Date: July 27, 2009

/ Minh-Quan K. Pham/  
Minh-Quan K. Pham, Ph.D.  
Registration No. 28,680

BLANK ROME LLP  
Watergate  
600 New Hampshire Avenue NW  
Washington, DC 20037  
Telephone: (202) 772-5800  
Facsimile: (202) 772-5858